~~H.P.A.~~

for Marsha Cohen

Position Paper on "Interim Re-Entry Periods"

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Prior to this time, I have not ventured my personal opinions on the question of "interim re-entry periods," at least not in any systematic way. I have preferred to wait until all the evidence was in. That point is now at hand. I should like to summarize the principal arguments on both sides, as I now see them: that is, the leading reasons why some feel the Task Group should issue a Special Report consisting of "emergency" or "temporary waiting periods"; and the leading reasons why others feel we should not. I should like to comment on what seem to me the strengths and weaknesses of each argument, and then draw the conclusions which I feel the weight of evidence dictates.

I. Arguments in favor of recommending "interim standards":

1. "If we don't do the job, someone less competent will." This was answered, with wit and irony, by a member of the Task Group in a recent letter (I will not name him, since it was a personal communication): " . . . those very sophisticated, intelligent formulas for rationale--4x4 = 16, as I remember those fantastically difficult and mathematically complex rationales from other subcommittees." To put the matter less sardonically: when relevant scientific information is absent, there is no special role for scientific competence to play. Any amateur can manipulate a simplistic, arbitrary formula as well as any expert.

2. "It doesn't really make any difference what we recommend, since our report will be merely advisory." In the first place, this argument is directly contradictory to the foregoing one. It implies that some other agency is wiser than we, and will correct our mistakes before actually promulgating any regulations. Secondly, and far more importantly, this argument represents an abdication of responsibility. Any recommendations which come out of this Task Group, either short-term or long-term, should be recommendations we have full confidence in, and would be happy to see translated directly into public policy.

3. "The Task Group would lose face if we were to back away from the Special Report at this late date." Even if this were true, it would not constitute a tenable argument. Our task is to protect and enhance worker safety, not our own pride. But I am now convinced the argument is not only weak, but untrue. Nothing would be better calculated to "lose face" for us than the appearance of unsound,and very possibly unsafe, re-entry periods under our authorship.

4. "It will be several years before solid data can become available; the public will not wait that long." Implicit in this argument are several assumptions, all of which bear examination.

   (a) What "public?" No one has suggested there is an emergency except the groups which filed a petition with the Department of Labor on September 1, 1972. They suggested that

800 farm workers are killed each year "as a result of improper use of pesticides," another 80,000 are poisoned, and all the rest are in "grave danger." These are false and irresponsible allegations and to dignify them is to compound the irresponsibility.

(b) Perhaps the closest thing to a persuasive argument in favor of issuing "interim re-entry periods" is that it may be a long while before evidence to support permanent regulations becomes available. If it were true, as some fear, that the Task Group's standard research protocols will take five years or more to carry out, I might find the foregoing argument very compelling indeed. But I do not believe that is going to be the practical thrust of our final report, at all. Controlled experiments in 1970 and 1971, which came very close to conforming with our protocols,took less than six months from the time they were first conceived to the final interpretation of the data by an independent government agency. These were pioneering studies. As such experiments become more and more standardized, there can be no doubt the time required for planning and execution will be considerably reduced.

(c) Some fear that there might be deliberate foot-dragging in carrying out the kinds of studies we recommend. But I have always assumed that we are going to make another recommendation which would carry a built-in incentive for such studies to be conducted with all deliberate speed: namely, that the types of information essential for the establishment of worker safety re-entry periods be made a precondition of registration, and reregistration of all "restricted use" pesticides, under FEPCA. Registrants would then have the same incentive to do the research speedily that they presently have under tolerance-setting requirements.

II. Arguments against recommending "interim re-entry periods."

1. We agreed to cooperate with the Department of Labor, on September 12, only after DOL representatives asserted that they were under "tremendous pressure" to "come up with numbers." I am now satisfied that there was little or no such pressure. The petitioning groups wanted some response, to be sure, but they were petitioning for many other things besides "temporary emergency safety time intervals." DOL action in terms of field sanitation, equipment inspection, reconstitution of the Agricultural Advisory Committee, etc., would have been responsive to the petition. The petitioners certainly were not asking for the issuance of unsafe waiting periods, or even periods about which there was any reasonable doubt.

2. I believe there was a "hidden agenda" we were not told about: a struggle between governmental agencies as to which would have primary jurisdiction over pesticide safety. Unwittingly, we lent ourselves to one side in this political tugging and hauling.

Yes

Late in the day as it may be, it is better to disassociate ourselves from such manipulation now than never.

3. The Special Report now circulating is studded with phrases such as these:

> "Many additional, well-designed field studies must be conducted if we are to establish with accuracy 'farm worker re-entry times' which will be valid . . . even for one crop grown throughout the United States."
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> ". . . the numerous gaps in appropriate knowledge have made the setting of precise standards an almost impossible task."
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> "Many more . . . monitoring studies must be conducted throughout the United States . . . before this Task Group can, with a high degree of accuracy, recommend scientifically sound re-entry periods."

Do the members of the group realize what they would be putting their names to, if such a report were to appear? Have they reflected on the meaning of such language as the above? These phrases mean that we tacitly admit many of our recommendations are probably inaccurate, invalid, imprecise, and scientifically unsound. How dare we make recommendations in which we have so little confidence? It may be disarming to admit to the world, in so many words, that our recommendations are dubious, but that does not make them any less dubious--and potentially dangerous.

4. The original charge to the Task Group provides for the possibility of recommending "interim re-entry standards"--but, upon my personal insistence, the following crucial qualification was added: "where possible . . . based upon existing knowledge." I asked that this

language be added because I had had prior experience, in California, with an attempt to establish worker re-entry periods in the absence of relevant information. When evidence began to become available, it was disquieting, to say the least, to find that the periods we had set on the basis of "scientific judgment" were almost always too short. I had no intention of repeating that experience on a national scale, and thus added the clarifying language to the Task Group charge. Let me review some of my earlier experiences.

(a) When we were initially trying to set emergency re-entry periods in California in 1970, it was our best "scientific judgment" that 5 days was an adequate waiting period for dioxathion (Delnav) in citrus. Subsequently, epidemiological investigation of worker poisonings forced us to revise the recommendation drastically upward: to 30 days. Still later, the residue work of Westlake, Gunther, and Carman confirmed the need for the longer period.

(b) It was originally assumed that seven days was an adequate waiting period for azinphosmethyl (Guthion) in citrus. This assumption was tested in a controlled experiment. Participants' blood cholinesterase levels were so lowered by exposure to emulsifiable concentrate (the form in which azinphosmethyl is almost exclusively used in California citrus), that we were obliged to recommend a re-entry period of 30 days.

(c) In 1970, another controlled study was conducted to test the assumption that "ethion poses no hazard to agricultural workers when used according to accepted usage patterns"--i.e., no restrictions on oranges, grapefruit, tangerines, and tangelos when used at a rate of 7.5 pounds AIA. To provide a margin of safety for participants, a seven day waiting period, rather than no waiting period at all, was tested. Again, cholinesterase levels were depressed (particularly by a wettable powder formulation which is most commonly used in California). And again residue analysis confirmed why this was so. Eight days after application, approximately 40 ppm of ethion were recovered from orange foliage to which 6.4 pounds AIA had been applied; approximately 14 ppm, 26 days after application. Ethion was therefore assigned a re-entry period of 30 days.

(d) In the first published version of California's permanent regulations (Notice of Hearing, January 8, 1971), phosalone (Zolone) on grapes was given a waiting period of 5 days, based on our best "scientific judgment." Soon afterward, the results of a field study became available to us. At 5 days, there were some 250 ppm of phosalone available on grape leaves; at 10 days, over 175; at 15 days, nearly 150; at 28 days, 100. In the final regulation, our initial figure of 5 days obviously had to be increased.

(e) In grapes, there were no label limitations on the use of azinphosmethyl, but it was our best "scientific judgment", extrapolated from citrus data, that the worker-protection period should be 14 days. Once again, our judgment was put to an empirical test by residue data which became available soon after the first version of California's regulation was published. The data showed that about 165 ppm of azinphosmethyl remained on grape leaves 14 days after application; 130 ppm, 21 days after application; 70 ppm, 42 days after application; etc. The facts obviously dictated that our judgment be revised in the direction of a longer re-entry period.

In short, the evidence from California, the one state with pertinent experience, shows that scientific intuition consistently erred in the direction of periods which were too short for positive protection. Note that these errors were not made by some indifferent, uninformed, catch-all group. They were made by a state advisory body very similar to the federal Task Group in competence and motivation. I and the others were genuinely concerned about health and safety; knowledgeable in appropriate disciplines; at pains to issue recommendations with a fully adequate margin of safety. Yet we were off the mark in almost every case--and not just a little bit.

Now I am chairman of another group, equally concerned, equally knowledgeable--and probably also equally fallible. It gives me the gravest pause. "Interim periods" based on judgment alone cannot always be right. That is self-evident. The question is, in what direction do they err. If there were any reason to assume that scientific intuition consistently errs in the direction of safety, it might be justifiable to promulgate waiting periods on the strength of mere intuition. But past experience is absolutely fatal to any such assumption.

5. It gives me grave pause, too, that the Task Group's recommendations for worker re-entry periods are so often shorter than EPA pre-harvest intervals (in more than 75% of the cases, by my calculation), and by such a wide margin (an average of 7.4 days as compared to 15.5). This is directly contrary to what experience has shown us in California. There have been longitudinal studies of the effects on harvest workers of six OP compounds in this state, to my knowledge. In five out of the six cases, it was found that PHI's were too short for effective worker protection, rather than too long. In other words, controlled experiments almost always reveal that re-entry periods need to be longer than anyone has previously assumed on the basis of label requirements or anything else. This, again, forces me to the conclusion that it is the better part of valor (and of safety) not to assume anything in this area, but to settle for nothing less than sound substantiating data.

6. What do I consider adequate substantiating data? Obviously, the optimum is a controlled experiment which tests the effect of an independent variable on a dependent variable when all intervening

variables are held constant. But I can conceive of useful information--not definitive, but useful--coming from other sources. For example, several members of a harvest crew may be demonstrably poisoned--verified by clinical examination, cholinesterase loss, and response to atropinization. If they were working in an orchard which had been sprayed with parathion, 2 pounds AIA, fourteen days previously, we have a relevant datum: fourteen days in this particular crop in this particular area may be sufficient for meeting tolerance, but it is not sufficient for worker safety.

An even better form of information, of course, is one which establishes the waiting period which is safe rather than unsafe. Let us say, for example, that another crew working in the same crop-area entered an orchard which had been sprayed with parathion, 2 pounds AIA, thirty days previously. Let us assume that they were members of a Community Studies on Pesticides long-term study, or for some other reason had undergone routine cholinesterase monitoring. Assume that all were at or near their pre-established baselines after working in the parathion-treated orchard. Although this situation would not have met all the criteria of a fully-controlled prospective experiment, it would provide clear circumstantial evidence that a thirty-day re-entry period contained a sufficient margin of safety.

In any and every case, whatever the details, certain types of information are basic--so basic they should be considered sine qua non. We need to know what was applied, to what crop, in what quantity, when, and with what effect on human well-being. If any of these is unknown, the test of minimum necessary knowledge is not met, in my opinion.

7. To put it another way, the test of "existing knowledge" adequate for the issuance of re-entry period regulations is not met if those regulations have to be based on extrapolation from one compound to another, one crop to another, one species to another. Almost all the 81 recommendations in the Special Report rest upon one or more of these forms of extrapolation.

8. An error on our part--or on the part of anyone else who ventures to set re-entry periods without the minimum necessary data--is no casual matter. This is not an academic question, not an exercise in curiosity, to be shrugged off with a jocular "Well, back to the old drawing board" if events prove us wrong. If error lies in the direction of a re-entry period which is too short (and I have shown, above, that this is the direction it most likely lies), the proof of our mistake will consist of worker poisonings--at least to the extent of significant cholinesterase inhibition, which we have agreed is a physiological change we are trying to avoid.

9. Worker safety is the sole direct concern of the Task Group. But I am sympathetic to those who advise against "tunnel vision," and who point out that worker safety is not altogether independent from or antithetical to other concerns. I am particularly impressed by Professor Richard Doutt's warning of what the practical effect will be if worker re-entry periods are issued which are shorter in most cases than existing pre-harvest intervals. Many growers are going to be confused, and in their confusion are often going to use the shorter re-entry period at harvest time, even if that is not the intention of the regulation. Not only are workers likely to be adversely affected, but pesticide users themselves, through condemnation of produce as over-tolerance, lawsuits, etc.

10. My final and most fundamental misgiving is the effect I believe the Special Report will have upon our final report. I accepted the chairmanship of this Task Group because I understood it had one purpose--a purpose I believed in, strongly, and still do--namely, to make comprehensive and detailed recommendations for how best to gather the information essential to the establishment of worker safety re-entry periods in which everyone can have complete confidence.

If "interim re-entry standards" were discussed at all, I expected that we might draw some conclusions from the handful of controlled studies which have been conducted to date. But for all the rest, I thought we would, in logic and consistency, be bound to say that the requisite information was unavailable, and therefore re-entry periods could not be set with an acceptable degree of confidence by ourselves or by anyone else.

If, now, the Task Group suggests re-entry periods for dozens of crop-compound combinations on which there is little if any cogent information, we have violated the heart of our own final report. We have done what we tell others they must not do. If we ourselves ignore our own research protocols, how can we expect others to honor them? Who is going to spend tens of thousands of dollars to design, conduct, and analyze the results of controlled studies, when we have shown the way to a method which takes only a few minutes and costs practically nothing? Could EPA require controlled studies as a precondition of registration if other co-equal departments of government have ruled, in effect, that they are not necessary?

11. I very much fear that we are well down the primrose path toward obviating the very reason for the existence of the Task Group. There are two options open to us, and only two so far as I can see. The easiest, no doubt, is to continue on the path we are following, mask our many misgivings, cross our fingers, issue a Special Report, and hope that everything somehow turns out for the best. In this event, I am now convinced, we will have effectively doomed the concept of re-entry periods based on prospective research designs.

    Perhaps we are extraordinarily wise, or extraordinarily lucky, and the 81 recommendations in our Special Report contain no errors--or, if there are errors, they are all in the direction of more safety than strictly necessary, and none less. But even in the one-in-a-million chance that this were so, there are more important questions at stake than any particular set of regulations. Is the setting of a re-entry period properly a scientific matter or is it something else? Should a problem which is intrinsically scientific in nature be solved by whatever means happen to be expedient, or can it be solved only with apposite evidence deriving from research methods capable of being replicated by other interested observers?

What is at stake is the principle of decision-making on scientific questions by the inductive method versus political pressure, hunches, biasses, and other vagaries. We of the Task Group may be above all suspicion and reproach, but we are not going to function in the field of re-entry periods forever. Who is to come after us? Perhaps someone not so expert, not so objective. Who is to say where their prejudices might lead? There is peril in a rule of men rather than laws, whether in politics or in science.

In a word, we are setting a precedent. If we compromise on principle, if we establish a rule of mortal men rather than scientific law at the very outset, it will be difficult if not impossible to change the rules later. The field for all time to come is likely to be marked by our methodological precedent. Not by what we may piously recommend in our final report, but by what we ourselves have actually done in our special report.

12. The other option open to us is more difficult, perhaps, in the short run, but I believe the long-term advantages to everyone concerned incomparably outweigh whatever may be the momentary difficulties. This alternative consists of leaving the primrose path, getting back on the track we were pursuing before we became diverted last September, affirming by both our words and our deeds

that worker re-entry periods should always be based on good quality dose-response data.

I don't want to sugar-coat what I am saying. Scientific responsibility is not an easy burden. It requires that we resist any temptation to go beyond the conclusions which can be sustained by facts--and it also requires something more. I believe we have a responsibility to use our influence to dissuade others who might yield to this temptation. For example, our responsibility might take the form of testifying, at an administrative hearing, against re-entry periods set by someone else in the absence of any existing data, or on the basis of data we know to be insufficient. (Since the Task Group will soon be dissolved, the obligation I am suggesting here is a personal rather than a collective one.)

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I am not necessarily saying that there should be no Special Report at all. I am well aware of the work that went into searching the literature, PRD files, and so forth. There is a way that this background research could be turned to a purpose perfectly consistent with the principles I have suggested above. We could describe, step by step, the work which the secretariat and the five subcommittes went through, the full processes of extrapolation and "scientific judgment," and then, despite our very best efforts, the serious limitations of the final results. We could explain, in every instance, what more was needed for conclusions in which we could have confidence. The whole special report could be presented as a case study in the present "state of the art" (which was part of our original charge). We could conclude by saying, in so many words and with all due immodesty, that if existing knowledge does not provide us with a defensible basis for national standards, it does not furnish anyone else such a basis, either.

A Special Report of this sort, far from colliding frontally with our final report, could be incorporated directly into the final document, as envisaged by Section VI-C of our original working outline. The alternative to such a modified Special Report would be to issue none at all, but I think this might pose more difficulties still. Earlier drafts of the Special Report have achieved a considerable circulation, for better or for worse. It might be more graceful to put into the same channels of circulation our amended thoughts, rather than to pretend they never existed.